DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 17, 1998

Our Reference Numbers: 96-1402, 97-1287 and 97-0964

Thomas S. Clement
Organon Teknika Corporation
100 Akzo Avenue
Durham, North Carolina 27712

Dear Mr. Clement:

Enclosed is a product license which authorizes Organon Teknika Corporation, U. S. License No. 956, to manufacture and sell in interstate and foreign commerce Human T-Lymphotropic Virus Types I and II (i.e., Vironostika[R] HTLV-I/II Microelisa System), an in vitro qualitative enzyme linked immunosorbent assay (ELISA) intended for use in the detection of antibodies to human T-lymphotropic virus types I and/or II in human serum or plasma as described in your product license application, Reference No. 96-1402.

As agreed to by Organon Teknika Corporation, the Phase IV studies outlined in your faxed letter of January 16, 1998 must be conducted and data submitted to the Center for Biologics Evaluation and Research (CBER).

You are requested to submit samples of each future master lot of the product with protocols consisting of a summary of essential manufacturing data inclusive of all applicable test results. No master lots of the product shall be distributed until notification of release is received from the Director of CBER.

The expiration dating for The Vironostika[R] HTLV-I/II Microelisa System is 14 months when stored at 2-8°C. Any request to extend this dating period must be accompanied by the results of ongoing stability studies.

Any lot of Human T-Lymphotropic Virus Types I and II found to fall outside of the approved specifications, including expiration dating periods, should be withdrawn from the market. In addition, any reports of significant product defects or product complaints concerning the use of the Vironostika[R] HTLV-I/II Microelisa System should be submitted to the Office of Compliance, CBER, HFM-650.

In addition, your requests to supplement your establishment license application to include areas for the manufacture of Human T-Lymphotropic Virus Types I and II at your Durham, North Carolina and Kinsington locations, Reference Numbers 97-1287 and 97-0964, have been approved. The information contained in these supplements will be included in your establishment license application file.

If you wish to prepare the licensed product or any of the ancillary components of the test kit other than as specified in your approved license applications, it may be necessary for you to submit a supplement to either your product or establishment license application for review and approval prior to implementation. If you wish to change any labeling, it will be necessary for you to submit a Transmittal of Labels and Circulars (Part I), Form FDA-2567, for review and approval before implementation.

A copy of your labeling submission is enclosed. Please submit three (3) copies of final printed labeling at the time of use and include Part II of the Transmittal of Labels and Circulars form (Form FDA-2567) with completed implementation information. In addition, you may wish to submit draft copies of the proposed introductory advertising and promotional labeling with a Form FDA-2567 to CBER, Advertising and Promotional Labeling Staff, HFM-202, 1401 Rockville Pike, Rockville, Maryland 20852-1448. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination accompanied by a Form FDA-2567. Promotional claims should be consistent with and not contrary to approved labeling. No comparative claims or claims of superiority over other similar products should be made unless data to support such claims are submitted to and approved by CBER.

Please acknowledge receipt of the enclosed product license by writing to the Director, Division of Blood Applications (HFM-370), Food and Drug Administration, CBER, c/o Document Control Center (HFM-99), Woodmont Office Center, Suite 200N, 1401 Rockville Pike, Rockville, Maryland 20852-1448.

Sincerely yours,

Jay S. Epstein, M.D.
Director
Office of Blood Research
and Review
Center for Biologics
Evaluation and Research

Jerome A. Donlon, M.D., Ph.D.
Director
Office of Establishment Licensing
and Product Surveillance
Center for Biologics
Evaluation and Research

Enclosures